

CLINICAL EVALUATION OF THE EFFICACY OF AN AYURVEDIC CREAM HEALMATE IN THE MANAGEMENT OF CRACKED HEELS (PAD-DARI)

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ABSTRACT:

To evaluate the efficacy of an Ayurvedic cream Healmate in the management of cracked heels with the prime objective to study to prevent the infection & promote healing and pain relieving of deep cracked heels. Ayurvedic drug in the cream base moisturizes the skin and also cure wound quickly healing and it cures irritation rapidly.

Cracked heels are commonly caused by dry skin (xerosis), and made more complicated if the skin around the rim of the heel is thick (callus). For most people this is a nuisance and a cosmetic problem but when the fissures or cracks are deep, they are painful to stand on and the skin can bleed - in severe cases this can become infected. In the present study 30 patients were selected randomly and treated with Healmate cream local application. The symptoms like red or flaky patches, peeling and cracked skin, itchy skin, bleeding or discharge from cracks were assessed before and after treatment. The study clearly indicated significant reduction in severity of symptoms.

Keywords: Cracked Heel, Anti-inflammatory, Callus, Flaky Patches, healmate.

INTRODUCTION: Cracked heels are a common foot problem that are often referred to as heel fissures^[2]. The skin is normally dry and may have a thick callus which appears as yellow or dark brown discoloured area of skin, especially along the inside border of the heel. Cracks in the skin are usually obvious.

What are the symptoms of cracked heels:^[2] If the cracks are bad enough there will be pain on weight bearing, that is not there when weight is off the heel. The edges or rim around the heel will generally have a thicker area of skin (callus)¹. The most common symptoms of dry, cracked heels and feet include:

- Red or flaky patches
- Peeling and cracked skin
- Itchy skin
- Bleeding or discharge from cracks

What causes cracked heels:

Some people tend to have a naturally dry skin that predisposes them to the cracks. The thickened dry skin (callus) around the heel that is more likely to crack is often due to mechanical factors that increase pressures in that area (e.g. the way you walk).

Other factors that can be involved in the cause of cracked heels include:

- prolonged standing (at work or home, especially on hard floors)
- being overweight (this increases the pressure on the normal fat pad under the heel, causing it to expand sideways - if the skin is not supple and flexible, the pressures to 'crack' are high)
- open back on the shoes (this allows the fat under the heel to expand sideways and increases the pressure to 'crack')
- some medical conditions predispose to a drying skin (eg autonomic neuropathy in those with diabetes leads

to less sweating; an underactive thyroid lowers the body's metabolic rate and there is a reduction in sweating, leading to a dryness of the skin)

- Bad eating habits.
- Irregular menstrual cycle.
- Age -Thick dry scaly skin lose elasticity with age and thus cracks have higher incidence with age.
- Skin conditions (eg psoriasis and eczema) Unhygienic circumstances or conditions Unhealthy, dry scaly skin due to climate or diseases Deficiency of vitamins, minerals and zinc.
- Idiopathic
- As the disease is due to *Ruksha guna* of *Vata dosha* following Ayurvedic Drugs in Cream base can act against the vitiated *Vata dosha*. *Shudha Hingul*, *Jatyadi tail*, *Ral (shudha)*, *Teel tail* & *Goghrit* may help to keep skin hydrated, soft which can induce proper healing and decrease the symptoms and may result in healing of Cracked feet

MATERIALS AND METHODS/ Composition of Ayurvedic Drugs^{[4][5]}

Materials – Following Ayurvedic Drugs in Cream base.

<i>Shudha Hingul</i>	-	100 gm
<i>Jatyadi tail</i>	-	100ml
<i>Ral (shudha)</i>	-	500gm
<i>Teel tail</i>	-	500ml
<i>Goghrit</i>	-	500ml

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The clinical trial was carried out in M. A. Podar Hospital. 30 patients of cracked heels satisfying inclusion criteria as described below were selected for study.

Criteria of selection of patients :

A) Inclusion criteria

- Both sexes of any age group.
- Randomly selected & well diagnosed of Cracked feet.
- Patients ready to abide trial procedure & to give informed consent.

B) Exclusion criteria :

- Severe bleeding Cracked feet.
- Chronic diabetic patients with diabetic foot.
- Gangrenous foot.
- Patients having any severe systemic diseases like Renal, Hepatic, Cardiac Disorders.

Ethical Consideration: The institutional ethics Committee permission has approved the study.

Ref. no.RAPN.V.-2/IEC/9333/2011

Written Consent: Written informed consent was taken from each patient after complete explanation of the procedure and satisfaction of his/her doubts.

Trial methodology

Description:

Location of study- R.A.Podar Hospital, Worli, Mumbai.

Duration of study-3 months.

Participant enrollments- 30 patients of any age diagnosed with cracked heels.

Subjects attending surgery OPD was screened for eligibility criteria. If a pt. satisfies the eligibility criteria, he/she was recruited into the study. After signing a written informed consent form.

At the baseline visit, detailed history including onset of disease was recorded. General and systemic examination was carried out to rule out any significant clini-

cal findings. Local examination was done in each pt. was supplied with a study medication stock for 3 wks. He was instructed to apply the cream twice in which sings & symptoms of Cracked feet was graded and scored as per specification given.

Each pt. was supplied with a study medication stock for 3 wks. He was instructed to apply the cream twice a day locally and bring back the empty containers of medicine or any unused medication at the next visit.

At each follow-up visit, pt. was assessed with respect to signs & symptoms of Cracked feet with photographic evidence recorded at baseline.

Pt. was asked for occurrence of adverse events & side-effects and the subsequent action was taken for its management and which was recorded.

All laboratory investigation was performed at baseline repeated after completion of treatment.

Assessment of parameters was the Principal investigators overall assessment which was graded as:

1-Excellent: improvement in all parameters.

2-Good: improvement in more than 2 parameters.

3-Average: improvement in less than 2 parameters.

4-Poor: No improvement.

Withdrawal criteria :

- Any patients which develops any adverse effects and side-effects like burning, itching, bleeding or any other complication during study, patient was withdrawn from the study & shifted for further active management.

- If the Investigator feels that the protocol has been violated or patient has become uncooperative.

Assessment of efficacy

Clinical Parameters –

1. Peeling & Cracked skin with Crack size(in length, width, depth)
2. Dry & Itchy skin
3. red & flaky patches
4. painful Cracked feet.

Specification of the efficacy parameters

1. Peeling and cracked heels:

Grade 0= no peeling and no cracks

Grade 1=superficial peeling & cracks

(with size upto 2x1x0.1 cm)

Grade 2=medium deep peeling & cracks

(with size 2.1 to 4.0 x 1.1-2.0x 0.1to 0.2cm)

Grade 3=deep peeling & cracks

(with size more than 4.1 x 2.1 x 0.2 cm).

2. Itchy skin:

Grade 0 = no itching

Grade 1= occasionally in a day

Grade 2= 2 to 3 times in a day

Grade 3= throughout the day

3. Red & flaky patches:

Grade 0 = no patches

Grade1= covered over less than half of the affected area.

Grade2= covered over half of the affected area.

Grade3= covered over all the affected area.

4. Painful Cracks:

Grade 0 = no Pain

Grade1= Pain over less than half of the affected area.

Grade2= Pain over half of the affected area.

Grade3= Pain over all the affected area.

Baseline Assessment:

General /systemic examination – T.P, R, B.P. Pallor, Cyanosis, Clubbing, Edema, R.S., C.V.S., C.N.S., genital examination.

DISCUSSION /OBSERVATIONS AND RESULTS

The data generated during the study can be grouped under the headings which is as follows:-

Clinical efficacy of therapy during the study:

TABLE 1: EFFECTS ON CLINICAL PARAMETERS

Sr.No.	Symptoms	BT	AT	Diff.	% of relief
1	Peeling & Cracked skin with Crack size	2.8133	1.0716	1.7417	61.91
2	Dry & Itchy skin	1.7667	0.4333	1.3334	75.47
3	Red & flacky patches	0.4667	0.2667	0.2	42.85
4	Painful Cracked heel	2.2933	0.9500	1.3433	58.57

Peeling & Cracked skin with Crack size:-

The % of relief observed in 40 patients was 61.91 %

Dry & Itchy skin:-

The % of relief observed in 40 patients for this symptom was 75.47%

Red & flacky patches:-

The % of relief observed in 40 patients for this symptom was 42.85%

Painful Cracked heel :-

The % of relief observed in 40 patients for this symptom was 58.57%

TABLE 2: TOTAL EFFECT OF THERAPY ON 60 PATIENTS OF MUSCULO-SKELETAL DISORDERS

Results	No. of pts.	%
Cured	10	25
Markedly improved	18	45
Improved	9	22.34
Unchanged	3	7.66

Out of the 40 patients observed- 10 patients (25%) showed 75-100% relief (Cured) in the symptoms.

8 patients (45%) were markedly improved (50-75%).

9 patients (22.34%) were improved (25-50%) in the symptoms.

3 (7.66%) of the 40 patients were found to get relief below 25%.

SUMMARY: The study entitled, Clinical Evaluation Of The Efficacy Of An Ayurvedic Cream Healmate In The Management Of Cracked Heels (Pad-Dari) aimed at studying the effects of Healmate cream local application in Cracked heel with the prime objective of To study the efficacy of Ayurvedic cream to prevent the infection & pain management of deep cracked heels.

The parameters taken for study were Peeling & Cracked skin with Crack size(in length, width, depth),Dry & Itchy skin, Red & flacky patches and Painful Cracked heel.

The results of the study were significant on all the parameters. 30 patients were selected and divided randomly and treated with Healmate cream local application.

Patients were treated as per decided plan & protocol of the study. Follow-up was taken for a period of 3 months. Before & after the treatment routine investigation of patient were done.Data thus generated was put to proper statistical analysis and following conclusion was drawn from the results obtained.

CONCLUSION: Patients started getting relief after 3 days in the 1st week & progressively got significant relief (Marked Improved) as per clinical symptoms presented. At the end of treatment there was no adverse effect found of treatment given to patients. Following conclusion can be drawn from the study. Clinical symptoms like Peeling & Cracked skin with Crack size (in length, width, depth), Dry & Itchy skin, Red & flakey patches and Painful Cracked heel decreases progressively.

Since the study was conducted for case study and research purpose so no any financial support taken from healmate.

1. Healmate cream proves its soothing and good healing action on Cracked heel.
2. Healmate cream moisturizes the skin and also cures wound of cracked skin of heel.
3. Healing of the Cracked heel indicates that Healmate cream protects skin from infection.
4. Healmate cream cures the Cracked heel completely.
5. It cures the irritation rapidly and relieves itching at cracked heel.

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Source of support: Nil

Conflict of interest: None

Declared

Cite this Article as : [K.Rajeshwar Reddy Clinical Evaluation of the Efficacy of An Ayurvedic Cream Healmate in the Management of Cracked Heels (Pad-Dari)] www.ijaar.in : IJAAR VOLUME III ISSUE II MAY-JUNE 2017 PAGE No:359-363